

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,
CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
IOWA, LOUISIANA, MASSACHUSETTS,
MICHIGAN, MINNESOTA, MONTANA,
NEVADA, NEW JERSEY, NEW MEXICO,
NEW YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND,
TENNESSEE, TEXAS, VERMONT,
VIRGINIA, WASHINGTON, WISCONSIN,
and the DISTRICT OF COLUMBIA
ex rel. URI BASSAN,

Plaintiffs,

v.

OMNICARE, INC.,

Defendant.

Case No. 15-CV-4179 (CM)

UNITED STATES OF AMERICA,

Plaintiff,

v.

OMNICARE, INC. and CVS HEALTH CORP.,

Defendants.

PRELIMINARY STATEMENT¹

Defendants Omnicare, Inc. (“Omnicare”) and CVS Health Corporation (“CVS”), by undersigned counsel, answer Plaintiff United States of America (the “Government”)’s

¹ Defendants have included headings for organizational purposes and have responded to any headings with substantive content as appropriate. To the extent any further response is required, Defendants deny the allegations in the headings of the Complaint.

Complaint. Specifically, in response to the numbered paragraphs included in the Complaint, Defendants admit, deny, or otherwise respond to the allegations as set forth below. All allegations are denied unless expressly admitted, and an admission to a portion of an allegation does not constitute an admission, either express or implied, to the remainder of the allegation.

1. Defendants admit that, from 2010 to 2018, Omnicare was one of the nation's largest providers of pharmacy services to long-term care facilities. Defendants deny the remaining allegations of Paragraph 1.

2. Defendants admit that CVS is Omnicare's indirect corporate parent. Defendants deny the remaining allegations of Paragraph 2.

3. Defendants deny the allegations of Paragraph 3.

4. Defendants admit that, although the numbers varied throughout the relevant time period, Omnicare currently operates approximately 160 pharmacies, and, on an annual basis, dispenses tens of millions of prescription drugs to approximately one million unique patients residing in long-term care facilities. Defendants deny the remaining allegations of Paragraph 4.

5. Defendants deny the allegations of Paragraph 5.

6. Defendants admit that Omnicare entered into a \$50 million settlement with the Department of Justice in 2012. The second and third sentences of Paragraph 6 otherwise purport to characterize or describe unidentified proceedings and documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations contained in the second and third sentences to the extent they are incomplete or inconsistent with the proceedings and documents. Defendants deny the remaining allegations of Paragraph 6.

7. Defendants deny the allegations of Paragraph 7.

8. Defendants deny the allegations of the first sentence of Paragraph 8. The second and third sentences purport to quote from, characterize, or describe documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations contained in the second and third sentences to the extent they are incomplete or inconsistent with the documents. The fourth sentence identifies an individual by title only and does not provide sufficient information for the individual to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations contained in the fourth sentence and, on that basis, deny them.

9. The first sentence of Paragraph 9 purports to offer a generalized assertion regarding unspecified audits; absent further specificity, Defendants lack sufficient knowledge and information to admit or deny the allegations and, on that basis, deny them. The second sentence purports to quote from, characterize, or describe a draft report, which speaks for itself; to the extent a response is required, Defendants deny the allegations contained in the second sentence to the extent they are incomplete or inconsistent with the draft report. The third sentence identifies an individual by title only and does not provide sufficient information for the individual to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations contained in the third sentence and, on that basis, deny them.

10. Paragraph 10 purports to offer generalized assertions regarding unspecified pharmacists and to describe statements and actions of individuals identified only by position; absent further specificity, Defendants lack sufficient knowledge and information to admit or deny the allegations and, on that basis, deny them.

11. Paragraph 11 purports to quote from, characterize, or describe unidentified documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

12. Defendants admit that Omnicare dispenses a variety of medications to various individuals. Defendants deny the remaining allegations of Paragraph 12.

13. Defendants deny the allegations of Paragraph 13.

14. Defendants admit that a percentage of long-term care residents have prescription medications covered by the Medicare, Medicaid, or TRICARE programs. Defendants deny the remaining allegations of Paragraph 14.

JURISDICTION AND VENUE

15. Paragraph 15 states conclusions of law to which no response is required.

16. Paragraph 16 states conclusions of law to which no response is required.

17. The first sentence of Paragraph 17 states conclusions of law to which no response is required. Defendants admit that Omnicare submitted claims for prescription drugs dispensed to individuals residing in long-term care facilities in this District.

PARTIES

18. Defendants admit that Plaintiff is the United States of America. The remaining allegations of Paragraph 18 purport to summarize a statutory and regulatory regime and to state conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 18 to the extent they are inconsistent with the underlying statutory or regulatory provisions.

19. Defendants admit that Relator was previously employed at an Omnicare pharmacy in New Mexico and that Relator purports to bring an action on behalf of the United

States and certain states, but deny the characterization and validity of the action. Defendants lack sufficient knowledge and information to admit or deny the remaining allegations of Paragraph 19 and, on that basis, deny them.

20. Defendants admit that, at the time this complaint was filed, Omnicare, Inc. was the nation's largest provider of pharmacy services to long-term care facilities and that it was a Delaware corporation with its principal place of business in Ohio. In December 2020, Omnicare Inc. ceased to exist, and its operations were assumed by Omnicare, LLC. Defendants admit that a percentage of Omnicare's drug dispensings were to beneficiaries of federal healthcare programs. Defendants admit that CVS is Omnicare's indirect corporate parent. Defendants deny any remaining allegations of Paragraph 20.

21. Defendants admit that, although the numbers varied throughout the relevant time period, CVS Health Corporation, through its subsidiaries, currently operates thousands of retail pharmacy locations and over 1000 MinuteClinic locations and offers health and prescription drug plans. Defendants further admit that CVS acquired Omnicare on August 18, 2015. Defendants deny any remaining allegations of Paragraph 21, including the allegations of the fourth sentence.

THE FALSE CLAIMS ACT

22. Paragraph 22 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 22 is denied to the extent it is inconsistent with the underlying statutes and regulations.

23. Paragraph 23 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required,

Paragraph 23 is denied to the extent it is inconsistent with the underlying statutes and regulations.

24. Paragraph 24 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 24 is denied to the extent it is inconsistent with the underlying statutes and regulations.

25. Paragraph 25 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 25 is denied to the extent it is inconsistent with the underlying statutes and regulations.

THE FEDERAL HEALTHCARE PROGRAMS

A. Medicare Part D

26. Paragraph 26 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 26 is denied to the extent it is inconsistent with the underlying statutes and regulations.

27. Paragraph 27 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 27 is denied to the extent it is inconsistent with the underlying statutes and regulations.

28. Defendants admit that when prescriptions are dispensed by pharmacies to Medicare Part D plan beneficiaries, the pharmacy may submit a claim to the Part D plan or its PBM electronically and that the information included on the electronic claim submission by the

pharmacy may include population of information regarding various demographic and claims-related information in NCPDP standard fields. Defendants further admit that the pharmacy may subsequently receive compensation from the Medicare Part D plan or its PBM if the medication is covered by the prescription drug benefit. The remaining allegations of Paragraph 28 purport to offer generalized assertions not applicable uniformly, and are denied.

29. Paragraph 29 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 29 is denied to the extent it is inconsistent with the underlying statutes and regulations.

30. Paragraph 30 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 30 is denied to the extent it is inconsistent with the underlying statutes and regulations.

31. The first, second, and fourth sentences of Paragraph 31 purport to summarize statutory or regulatory provisions or agency guidance and to state conclusions of law to which no response is required; to the extent a response is required, the allegations of the first, second, and fourth sentences are denied to the extent they are inconsistent with the underlying statutes, regulations, or agency guidance. The allegations of the third sentence purport to characterize CMS's administration of the Part D benefit, and Defendants do not have information sufficient to confirm or deny what is "integral" to CMS; to the extent the allegations characterize statutory or regulatory provisions, the allegations are denied to the extent they are inconsistent with the underlying statute or regulations.

32. Paragraph 32 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 32 is denied to the extent it is inconsistent with the underlying statutes and regulations.

33. Paragraph 33 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 33 is denied to the extent it is inconsistent with the underlying statutes and regulations.

34. Paragraph 34 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 34 is denied to the extent it is inconsistent with the underlying statutes and regulations.

35. Paragraph 35 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 35 is denied to the extent it is inconsistent with the underlying statutes and regulations.

36. Paragraph 36 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 36 is denied to the extent it is inconsistent with the underlying statutes and regulations.

37. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 37 and, on that basis, deny them.

38. Paragraph 38 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 38 is denied to the extent it is inconsistent with the underlying statutes and regulations.

39. Paragraph 39 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 39 is denied to the extent it is inconsistent with the underlying statutes and regulations.

40. Paragraph 40 states conclusions of law to which no response is required. To the extent a response is required, the allegations of Paragraph 40 are denied.

41. Paragraph 41 purports to summarize statutory or regulatory provisions or agency guidance or actions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 41 is denied to the extent it is inconsistent with the underlying statutes, regulations, guidance, or actions.

42. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 42 and, on that basis, deny them.

43. Paragraph 43 purports to summarize regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 43 is denied to the extent it is inconsistent with the underlying regulations.

B. Medicaid

44. Paragraph 44 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required,

Paragraph 44 is denied to the extent it is inconsistent with the underlying statutes and regulations.

45. Paragraph 45 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 45 is denied to the extent it is inconsistent with the underlying statutes and regulations.

46. Paragraph 46 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 46 is denied to the extent it is inconsistent with the underlying statutes and regulations.

47. Defendants admit that when prescriptions are dispensed by pharmacies to Medicaid beneficiaries, the pharmacy may submit a claim to Medicaid or its benefit administrator and that the information included may include various demographic and claims-related information in NCPDP standard fields. The remaining allegations of Paragraph 47 purport to offer generalized assertions about “typical” claims, and are denied.

48. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 48 and, on that basis, deny them. To the extent Paragraph 48 purports to summarize statutory or regulatory provisions or to state conclusions of law, no response is required. To the extent a response is required, Paragraph 48 is denied to the extent it is inconsistent with the underlying statutes and regulations.

49. Paragraph 49 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required,

Paragraph 49 is denied to the extent it is inconsistent with the underlying statutes and regulations.

50. Paragraph 50 states conclusions of law to which no response is required. To the extent a response is required, the allegations of Paragraph 50 are denied.

51. Paragraph 51 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 51 is denied to the extent it is inconsistent with the underlying statutes and regulations.

52. Defendants lack sufficient knowledge and information to admit or deny the allegations of the first sentence of Paragraph 52 and, on that basis, deny them. To the extent Paragraph 52 purports to summarize statutory or regulatory provisions or to state conclusions of law, no response is required. To the extent a response is required, Paragraph 52 is denied to the extent it is inconsistent with the underlying statutes and regulations.

53. The first and third sentences of Paragraph 53 purport to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, the first and third sentences of Paragraph 53 are denied to the extent they are inconsistent with the underlying statutes and regulations. Defendants lack sufficient knowledge and information to admit or deny the allegations of the second sentence of Paragraph 53 and, on that basis, deny them.

54. Defendants admit that, for certain covered claims, pharmacies may receive reimbursement from third party administrators of Medicaid managed care plans for medications dispensed to members of Medicaid managed care plans. Defendants deny the remaining allegations of Paragraph 54.

55. Defendants admit that for some prescriptions dispensed to beneficiaries of Medicaid managed care plans, the prescription drug claim may include the beneficiary's Medicaid identification number. Defendants deny the remaining allegations of Paragraph 55.

56. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 56 and, on that basis, deny them.

57. Paragraph 57 states conclusions of law to which no response is required. To the extent a response is required, the allegations in Paragraph 57 are denied.

58. Paragraph 58 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 58 is denied to the extent it is inconsistent with the underlying statutes and regulations.

59. Paragraph 59 purports to quote and/or summarize an unspecified contractual document, which speaks for itself. To the extent a response is required, Defendants deny the allegations of Paragraph 59 to the extent they are incomplete or inconsistent with the underlying document.

C. TRICARE

60. The first and second sentences of Paragraph 60 purport to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, the first and second sentences of Paragraph 60 are denied to the extent they are inconsistent with the underlying statutes and regulations. Defendants lack sufficient knowledge and information to admit or deny the allegations of the third sentence of Paragraph 60 and, on that basis, deny them.

61. Defendants admit that for prescriptions filled for TRICARE members, Omnicare may submit electronic data regarding the prescription and, in response, receive information about the administration of the benefit. Defendants lack sufficient knowledge and information to admit or deny the allegations regarding “the PBM” and, on that basis, deny them. Defendants deny the remaining allegations of Paragraph 61.

62. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 62 and, on that basis, deny them.

63. Paragraph 63 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 63 is denied to the extent it is inconsistent with the underlying statutes and regulations.

64. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 64 and, on that basis, deny them.

65. Paragraph 65 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 65 is denied to the extent it is inconsistent with the underlying statutes and regulations.

FACTUAL BACKGROUND

I. Prescription Drugs Can Only Be Dispensed Pursuant To Valid Prescriptions Under The Supervision Of A Physician.²

66. Paragraph 66 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required,

² Heading I states conclusions of law to which no response is required. To the extent a response is required, the allegations in Heading I are denied.

Paragraph 66 is denied to the extent it is inconsistent with the underlying statutes and regulations.

67. Paragraph 67 purports to explain the rationale for and summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 67 is denied to the extent it is inconsistent with the underlying statutes and regulations.

68. Defendants admit that controlled substances are identified and regulated by the Controlled Substances Act and that not all prescription drugs are controlled substances. The second sentence of Paragraph 68 is the Government's characterization of its Complaint, to which no response is required.

69. Paragraph 69 states conclusions of law to which no response is required. To the extent a response is required, Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 69 and, on that basis, deny them.

70. Paragraph 70 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 70 is denied to the extent it is inconsistent with the underlying statutes and regulations.

II. Omnicare Dispensed Prescription Drugs To Residents Of Different Types Of Long-Term Care Facilities Offering Differing Levels Of Medical Care.³

71. Defendants admit that Omnicare dispenses primarily to long-term care facilities. Defendants deny the remaining allegations of Paragraph 71.

³ Defendants admit that Omnicare dispensed medications to residents of different types of long-term care facilities.

A. Skilled Nursing Facilities Provide Around-The-Clock Medical Care Supervised By Physicians.⁴

72. Defendants admit that a significant portion of prescription medications dispensed by Omnicare have been for residents of skilled nursing facilities and that the portion has varied over time. The second sentence of Paragraph 72 purports to generalize “typical” services of SNFs of which Defendants lack sufficient knowledge and information to admit or deny the allegations and, on that basis, deny them. To the extent the second sentence purports to summarize statutory or regulatory provisions, the second sentence is denied to the extent it is inconsistent with the underlying statutes and regulations.

73. Paragraph 73 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 73 is denied to the extent it is inconsistent with the underlying statutes and regulations.

B. Assisted Living Facilities And Other Residential Facilities Provide Limited Or No Medical Care.⁵

74. Defendants admit that Omnicare dispenses prescription drugs to residents of long-term care facilities. The second sentence of Paragraph 74 purports to excerpt information from an unidentified document, which speaks for itself. To the extent a response is required,

⁴ Heading A purports to offer generalized assertions regarding facilities in unspecified locations during an unspecified period of time; absent further specificity, Defendants lack sufficient knowledge and information to admit or deny the allegations and, on that basis, deny them. To the extent Heading A purports to summarize statutory or regulatory provisions, Heading A is denied to the extent it is incomplete or inconsistent with the underlying statutes and regulations.

⁵ Defendants lack sufficient knowledge and information to admit or deny the allegations in Heading B and, on that basis, deny them. To the extent Heading B purports to summarize statutory or regulatory provisions or licensing requirements, Heading B is denied to the extent it is incomplete or inconsistent with the underlying statutes, regulations, and/or licensing requirements.

Defendants deny the allegations in the second sentence to the extent they are incomplete or inconsistent with the underlying document. Defendants lack sufficient knowledge and information to admit or deny the allegations of the third sentence of Paragraph 74 and, on that basis, deny them.

75. Paragraph 75 purports to offer generalized assertions regarding what facilities “typically” offer and “may” provide. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 75 and, on that basis, deny them.

76. Paragraph 76 purports to offer generalized assertions regarding undefined “homes” and what they “typically” or “sometimes” provide. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 76 and, on that basis, deny them.

77. Defendants admit that assisted living facilities are among the residential communities that Omnicare serves. The allegations of the first sentence of Paragraph 77 are otherwise denied. Defendants lack sufficient knowledge and information to admit or deny the allegations in the second sentence and, on that basis, deny them. The remaining allegations of Paragraph 77 purport to excerpt information from the cited document, which speaks for itself; Defendants deny the allegations to the extent they are incomplete or inconsistent with the underlying document.

78. Defendants admit that some residential facilities can contain different types or levels of care. Defendants lack sufficient knowledge and information to admit or deny the remaining allegations of Paragraph 78 and, on that basis, deny them.

79. Defendants deny the first sentence of Paragraph 79. The second sentence is the Government’s characterization of its Complaint, to which no response is required.

1. Assisted Living Facilities Do Not Provide Routine Physician Review Of Residents' Prescription Drug Regimen.⁶

80. Paragraph 80 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 80 is denied to the extent it is inconsistent with the underlying statutes and regulations.

81. Defendants admit that specific laws concerning assisted living facilities vary from state to state. The allegations of the first sentence of Paragraph 81 are otherwise denied. The remaining allegations of Paragraph 81 purport to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required; to the extent a response is required, the allegations are denied to the extent they are inconsistent with the underlying statutes and regulations.

82. Paragraph 82 purports to offer generalized assertions regarding unspecified assisted living facilities. Defendants lack sufficient knowledge and information to admit or deny the allegations in Paragraph 82 and, on that basis, deny them.

83. Defendants lack sufficient knowledge and information to admit or deny the allegations in Paragraph 83 and, on that basis, deny them.

2. Assisted Living Facility Residents' Prescription Drug Therapy Must Be Closely Monitored By A Physician To Avoid Dangerous Adverse Effects.⁷

⁶ Heading 1 purports to offer generalized assertions regarding all assisted living facilities; absent further specificity, Defendants lack sufficient knowledge and information to admit or deny the allegations of Heading 1 and, on that basis, deny them.

⁷ Heading 2 purports to offer a generalized assertion regarding the health of Assisted Living Facility residents. Defendants lack sufficient knowledge and information to admit or deny the allegations of Heading 2 and, on that basis, deny them.

84. Paragraph 84 purports to offer generalized assertions regarding unspecified drugs, drug therapy, health conditions, drug interactions, and side effects. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 84 and, on that basis, deny them.

85. Paragraph 85 purports to excerpt information from the cited study, which speaks for itself; to the extent a response is required, Defendants deny the allegations of Paragraph 85 to the extent they are incomplete or inconsistent with the study.

86. The first sentence of Paragraph 86 purports to offer generalized assertions regarding the health of ALF residents and the intent of specific facilities. Defendants lack sufficient knowledge and information to admit or deny the allegations of the first sentence and, on that basis, deny them. The remaining allegations purport to excerpt information from the cited study, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the study.

87. Paragraph 87 purports to offer generalized assertions regarding certain health conditions, treatments, and impact of treatment. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 87 and, on that basis, deny them.

88. The first sentence of Paragraph 88 purports to offer generalized assertions regarding the health of ALF residents. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 88 and, on that basis, deny them.

III. Prescriptions For Residents Of ALFs And Other Residential Facilities Are Only Valid For A Specified Number Of Fills And A Certain Period Of Time.⁸

⁸ Heading III purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Heading III to the extent they are inconsistent with the underlying statutes and regulations.

89. Paragraph 89 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 89 is denied to the extent it is inconsistent with the underlying statutes and regulations.

A. A Prescription Must Specify The Total Quantity Prescribed Or The Number Of Refills Authorized.⁹

90. Defendants admit that specific state requirements for dispensing medication may vary. Accordingly, requirements must be viewed by reference to specific state law, and therefore Omnicare is without information sufficient to admit or deny what is “typically” required. Paragraph 90 further purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 90 is denied to the extent it is inconsistent with the underlying statutes and regulations.

91. Paragraph 91 purports to identify the intent and/or import of certain requirements in unidentified states or state statutes and regulations and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 91 is denied to the extent it is inconsistent with the underlying statutes and regulations.

92. The first sentence in Paragraph 92 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in the first sentence of Paragraph 92 to the extent they are inconsistent with the underlying statutes and regulations. As to the second

⁹ Heading A purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Heading A to the extent they are inconsistent with the underlying statutes and regulations.

sentence, Omnicare admits that certain hard copy prescriptions that resemble those that may be carried by a patient to a local retail pharmacy are sometimes referred to by some Omnicare employees as “retail-type” prescriptions. Defendants deny any remaining allegations of Paragraph 92.

93. Paragraph 93 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 93 is denied to the extent it is inconsistent with the underlying statutes and regulations. Omnicare admits that states may permit medication authorization to be communicated verbally and that the specific state requirements for verbal orders vary.

B. A Prescription Expires After A Specified Period, Usually One Year.¹⁰

94. Paragraph 94 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 94 is denied to the extent it is inconsistent with the underlying statutes and regulations.

95. Paragraph 95 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 95 is denied to the extent it is inconsistent with the underlying statutes and regulations. Omnicare admits that state law may regulate when a prescription can be refilled and that the specific state laws and regulations vary.

¹⁰ Heading B purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Heading B to the extent they are inconsistent with the underlying statutes and regulations.

96. Paragraph 96 purports to characterize the intent and/or import of unidentified statutes or regulations in unidentified states and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 96 is denied to the extent it is inconsistent with the underlying regulations and state laws.

97. Paragraph 97 purports to quote from, characterize, and describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document. Defendants deny any remaining allegations of Paragraph 97.

98. Defendants deny the allegations of Paragraph 98.

C. Because SNF Resident Care Is Supervised By Physicians, Some States Permit Pharmacies To Dispense Prescription Drugs To SNFs Until The Physician Discontinues The Prescription.¹¹

99. Paragraph 99 purports to characterize the intent and/or summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 99 is denied to the extent it is inconsistent with the underlying statutes or regulations.

100. Paragraph 100 purports to summarize statutory or regulatory provisions and to state conclusions of law to which no response is required. To the extent a response is required, Paragraph 100 is denied to the extent it is inconsistent with the underlying statutes and regulations.

IV. As Omnicare Became The Country's Largest Long-Term Care Pharmacy, It Failed To Put In Place The Staffing, Controls, And Training Necessary To

¹¹ Heading C purports to characterize the intent and/or import of certain state statutes or regulations and to state conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Heading C to the extent they are inconsistent with the underlying statutes or regulations.

Ensure Legal Dispensing Practices.¹²

101. Defendants admit that, prior to 2010, Omnicare acquired American Mediserve Corporation, American Pharmaceutical Services Inc., NCS HealthCare Inc., and NeighborCare. Defendants deny the remaining allegations of Paragraph 101.

102. Defendants admit that Omnicare pharmacies are located in 46 states and, while the numbers varied throughout the relevant time period, Omnicare currently operates approximately 160 pharmacies, and, on an annual basis, dispenses tens of millions of prescription drugs to approximately one million unique patients residing in long-term care facilities. Defendants admit that, in the second quarter of 2015, Omnicare dispensed approximately 26 million prescriptions. Defendants deny the remaining allegations of Paragraph 102.

103. Defendants deny the allegations of Paragraph 103.

104. Defendants deny the allegations of Paragraph 104.

105. Defendants deny the allegations of the first sentence of Paragraph 105. Omnicare admits that it engaged in automation to enhance the efficiency and accuracy of certain aspects of medication dispensing. Omnicare admits that the 2014 10-K contains the stated language. Defendants deny any remaining allegations of Paragraph 105.

106. Omnicare admits that certain aspects of local pharmacy operations were appropriately overseen by local pharmacies. Defendants deny the remaining allegations of Paragraph 106.

¹² Defendants deny the allegations of Heading IV.

A. Omnicare Pharmacies Were Under Constant Pressure To Dispense Huge Volumes Of Drugs.¹³

107. The first two sentences of Paragraph 107 contain characterizations and generalizations regarding Omnicare pharmacies. Omnicare admits that the volume of prescriptions it dispensed varied throughout the relevant period and by pharmacy. The bullets in Paragraph 107 purport to be statements of individuals identified by title only and do not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations contained in the bullets and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 107.

108. Defendants deny the allegations of Paragraph 108.

109. Paragraph 109 purports to characterize and contain statements of individuals identified by title only and does not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations of Paragraph 109 and, on that basis, deny them.

B. Omnicare Failed To Effectively Train Pharmacy Staff On Core Dispensing Obligations.¹⁴

110. Defendants deny the allegations of Paragraph 110.

111. Omnicare admits that some portion of the training provided to Omnicare pharmacy employees was done on the job. Defendants deny the remaining allegations of Paragraph 111.

112. Paragraph 112 purports to characterize and contain statements of individuals identified by title only and does not provide sufficient information for the individuals to be

¹³ Defendants deny the allegations of Heading A.

¹⁴ Defendants deny the allegations of Heading B.

identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them.

113. Defendants deny the allegations of the first sentence of Paragraph 113. The second sentence of Paragraph 113 purports to quote from, characterize, or describe testimony from an unidentified individual. That testimony speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the testimony.

C. Omnicare's Compliance Program Failed To Ensure That Pharmacies Complied With Core Dispensing Obligations.¹⁵

114. Defendants deny the allegations of Paragraph 114.

115. Omnicare admits that it had a Compliance Department during the Relevant Period and that the structure and makeup of the Compliance Department varied over time. Defendants deny the remaining allegations of Paragraph 115.

116. Defendants deny the allegations of the first, second, and third sentences of Paragraph 116. The fourth sentence of Paragraph 116 purports to quote from, characterize, or describe unidentified documents or testimony, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents or testimony.

117. Paragraph 117 purports to offer generalized assertions regarding undefined "regular" or "comprehensive" audits. Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 117 and, on that basis, deny them.

¹⁵ Defendants deny the allegations of Heading C.

118. Defendants admit that Omnicare has been subject to several federal investigations and lawsuits, one of which involved controlled substances and resulted in a 2012 settlement with the Department of Justice. Defendants further admit that Omnicare is aware that the federal Controlled Substances Act regulates dispensing of controlled substances. The remaining allegations in Paragraph 118 purport to characterize the Government's claims in that case. Defendants are without sufficient knowledge or information to admit or deny anything other than what was set forth in the settlement agreement and deny the allegations to the extent they are incomplete or inconsistent with the settlement agreement.

119. Defendants admit that Omnicare has faced other lawsuits and False Claims Act investigations, resulting in settlements in 2006, in the amount of \$49.5 million; in 2009, in the amount of \$98 million; in 2014, in the amounts of \$4.19 million and \$124.24 million; in 2016, in the amounts of \$28.1 million and \$2.24 million; and in 2017, in the amounts of \$8 million and \$23 million. The remainder of the allegations of Paragraph 119 purport to characterize the allegations and/or content of the settlement agreements; Defendants deny the remainder of the allegations of Paragraph 119 to the extent they are incomplete or inconsistent with the settlement agreements, which speak for themselves.

120. Defendants admit that during the Relevant Time Period, CVS Health Corp. entered into a Corporate Integrity Agreement with the Department of Health and Human Services pertaining to the operations of Omnicare, Inc. and a separate Corporate Integrity Agreement with the Department of Health and Human Services pertaining to CVS Caremark's PBM operations. Those agreements speak for themselves, and Defendants deny the allegations to the extent they are incomplete or inconsistent with the agreements. Defendants deny the remaining allegations of Paragraph 120.

V. Omnicare's Computer Systems Allowed Prescriptions To "Roll Over."¹⁶

121. Defendants admit that Omnicare pharmacies use two different computer systems to record and track information on prescriptions and dispenses: OmniDX and Oasis. Defendants further admit that, although the percentage has changed over time, approximately 60% of Omnicare pharmacies currently use OmniDX. Defendants deny the remaining allegations of Paragraph 121.

122. Defendants deny the allegations of Paragraph 122.

A. The Prescription Order Entry Process.

123. Defendants admit that the Order Entry Technician has primary responsibility for entering prescription information for new prescriptions into the OmniDX or OASIS system. Defendants further admit that the Order Entry Technician has primary responsibility for entering quantity or refills if required. Defendants admit that Omnicare's computer systems used the information entered by the Order Entry Technician for certain calculations and prescription tracking. Defendants further admit that some information entered into OmniDX or OASIS by the Order Entry Technician may be included in information submitted to third-party payors for certain prescriptions. Defendants deny any remaining allegations of Paragraph 123.

124. Defendants admit that accurate entry of authorized refills or total quantity prescribed, if written by the prescriber, was critical to ensuring any such instructions were accurately adhered to. Defendants deny the remaining allegations of Paragraph 124.

¹⁶ Heading V contains allegations regarding the undefined term "Roll Over," and, without definition, Defendants are unable to admit or deny the allegations of Heading V. Defendants admit that OmniDX and OASIS contained functionality that, in certain circumstances, permitted prescriptions to "roll over," as that term was used internally at Omnicare.

125. Defendants admit that once information regarding a prescription was entered into Omnicare's computer system, the prescription was routed to Pharmacist Verification 1 or "PV1" for pharmacist review, which could include checking for allergies, drug interactions, duplicate therapies, and contraindications. Defendants further admit that subsequent refills of a prescription did not always go through the PV1 process but might in certain circumstances, including if there was new information regarding patient allergies or drug regimen. Defendants deny the remaining allegations of Paragraph 125.

126. Defendants deny the allegations of Paragraph 126.

B. Omnicare Automatically "Rolled Over" Prescriptions In OmniDX Unless The Retirement Field Was Turned On.¹⁷

127. Defendants admit that there was a setting in OmniDX that was designated the "Retirement" field and that it could be set at the facility level. Defendants deny the remaining allegations of Paragraph 127.

128. Defendants admit that "retirement" was first designated to differentiate between types of facilities and the type of dispensing authority permitted. Defendants deny that "retirement" was always used in that way. Defendants deny the remaining allegations in the first and second sentences of Paragraph 128. The third sentence of Paragraph 128 purports to quote from, characterize, or describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

129. Defendants deny the allegations of Paragraph 129.

¹⁷ Defendants deny the allegations of Heading B.

130. Defendants admit that, when the Retirement field was set to Y, OmniDX required entry of a number in either the Refills Allowed field or Max Allowable Refills field, otherwise the system would not permit further processing of the prescription for dispensing. Defendants deny any remaining allegations of Paragraph 130.

131. Defendants admit that each time a pharmacy dispensed a prescription, the number populated in the Refills Allowed field in OmniDX typically decreased by one. Defendants further admit that if the Retirement field was set to Y, when the Refills Allowed field reached zero, OmniDX would not permit pharmacy staff to process additional refills for dispensing without additional steps and that OmniDX generated a prompt requiring pharmacy staff to take action, including to obtain a new prescription. Defendants deny any remaining allegations of Paragraph 131.

132. Defendants admit that if the Retirement field was set to N, the OmniDX system did not require a value to be entered in the Refills Allowed field and that, if there was no number manually entered into the Refills Allowed field, OmniDX would populate a value. Defendants deny the remaining allegations of Paragraph 132.

133. Defendants admit that OmniDX used the RX Issue Date field in calculating the expiration date for an order. Defendants further admit that, if an order is expired, OmniDX would not permit pharmacy staff to process additional refills for dispensing after the expiration date without additional steps, and, if a new prescription request was made after the expiration date, OmniDX generated a prompt requiring pharmacy staff to take action, including to obtain a new prescription. Defendants deny the remaining allegations of Paragraph 133.

134. Defendants deny the allegations of Paragraph 134.

C. Omnicare Automatically “Rolled Over” Prescriptions In Oasis Unless The Prescribed Quantity Required Field Was Turned On.¹⁸

135. Defendants admit that there was a field in Oasis designated “prescribed quantity required.” Defendants deny the remaining allegations of Paragraph 135.

136. Defendants deny the allegations of Paragraph 136.

137. Defendants admit that, in Oasis, when the Prescribed Quantity Required field was turned on (i.e., set to “Y”), Oasis required pharmacy staff to enter the total prescribed quantity or authorized refills at order entry, and the system would use that number to track the remaining prescribed quantity or refills after each fill. Once that number of refills was exhausted, Oasis prevented any additional dispensing without further action by pharmacy staff. Defendants deny the remaining allegations of Paragraph 137.

138. Defendants admit that when the Prescribed Quantity Required field was off for a particular customer, the Oasis system did not require pharmacy staff to populate the prescribed quantity or authorized refills fields at order entry. Defendants deny the remaining allegations of Paragraph 138.

D. Omnicare’s Cycle Fill System Allowed Prescriptions To “Rollover” In OmniDX.¹⁹

139. Defendants admit that prescription refills could be initiated “on demand” or, at some Omnicare pharmacies for some facilities, on a “cycle-fill” basis. Defendants further admit that on demand refills are initiated upon request from the facility. Defendants admit that cycle fill is a process by which a pharmacy fills certain medications at a pre-determined cadence for

¹⁸ Defendants deny the allegations of Heading C.

¹⁹ Defendants deny the allegations of Heading D.

delivery to the facility at the same time. Defendants deny the remaining allegations of Paragraph 139.

140. Defendants admit that many facilities that utilize cycle fill are assisted living facilities and that cycle fill may promote efficiency for certain tasks. The second sentence of Paragraph 140 purports to quote from, characterize, or describe unidentified marketing materials, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the materials. Defendants deny the remaining allegations of Paragraph 140.

141. Defendants deny the allegations of Paragraph 141.

OMNICARE'S FRAUDULENT CONDUCT²⁰

I. Omnicare Routinely Dispensed Prescription Drugs To Federal Healthcare Program Beneficiaries Residing In ALFs And Other Residential Facilities Without Current, Valid Prescriptions.²¹

142. Defendants deny the allegations of Paragraph 142.

143. Defendants deny the allegations of Paragraph 143.

144. Defendants deny the allegations contained in the sentences prior to the bullets in Paragraph 144. The bullets in Paragraph 144 identify individuals by title only and do not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations contained in the bullets and, on that basis, deny them.

145. Defendants deny the allegations of Paragraph 145.

146. Defendants deny the allegations of Paragraph 146.

²⁰ Defendants deny the allegations of the Heading.

²¹ Defendants deny the allegations of Heading I.

147. Defendants deny the allegations of Paragraph 147.

148. Defendants deny the allegations of Paragraph 148.

A. Omnicare Disregarded Quantity And Time Limits On Prescriptions, “Rolling Over” Prescriptions For Drugs Distributed To Residents Of Over 3,000 ALFs And Other Residential Facilities.²²

149. Defendants deny the allegations of the first four sentences of Paragraph 149. The final sentence of Paragraph 149 contains a characterization of the Government’s Complaint, to which no response is required.

150. Defendants deny the allegations of Paragraph 150.

151. Paragraph 151 contains a characterization of the Government’s Complaint, to which no response is required.

1. Omnicare Pharmacies Using OmniDX “Rolled Over” Prescriptions For Drugs Dispensed To Residents Of At Least 1,256 ALFs And Other Residential Facilities.²³

152. Defendants deny the allegations of Paragraph 152.

153. Defendants deny the allegations of Paragraph 153.

154. Defendants admit that, during the Relevant Time Period, the responsibility for setting up each facility varied and may have included pharmacy personnel. Defendants deny the remaining allegations of Paragraph 154.

155. Paragraph 155 contains a generalized assertion as to the knowledge of “most” pharmacists. Absent further specificity, Defendants lack sufficient knowledge and information to admit or deny the allegations of Paragraph 155 and, on that basis, deny them.

²² Defendants deny the allegations of Heading A.

²³ Defendants deny the allegations of Heading 1.

156. The allegations of Paragraph 156 purport to quote or characterize information from the cited documents, exhibits created by counsel for the Government purportedly based on data produced by Omnicare. The exhibits—and the underlying data—each speak for themselves. Defendants deny the allegations of Paragraph 156 to the extent they incorrectly characterize the information in the exhibit or inaccurately compile or characterize the data on which the documents purport to be based. Defendants deny that the facilities chronicled in the cited documents were improperly designated.

157. Defendants deny the allegations of Paragraph 157.

2. Omnicare Pharmacies Using Oasis “Rolled Over” Prescriptions For Drugs Dispensed To Residents Of At Least 510 ALFs And Other Residential Facilities.²⁴

158. Defendants deny the allegations of Paragraph 158.

159. Defendants deny the allegations of the first sentence of Paragraph 159. The second sentence of Paragraph 159 purports to characterize unidentified documents and to identify individuals by title only and does not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations contained in the second sentence and, on that basis, deny them.

160. Paragraph 160 purports to include statements of individuals identified by title only; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 160 and, on that basis, deny them.

161. The allegations of Paragraph 161 purport to quote or characterize information from the cited documents, exhibits created by counsel for the Government purportedly based on data produced by Omnicare. The exhibits—and the underlying data—each speak for themselves.

²⁴ Defendants deny the allegations of Heading 2.

Defendants deny the allegations of Paragraph 161 to the extent they incorrectly characterize the information in the exhibit or inaccurately compile or characterize the data on which the document purports to be based. Defendants deny that any of the facilities chronicled in the cited documents were improperly coded or that prescriptions were dispensed without a valid prescription.

3. Through Its Cycle Fill Program, Omnicare Pharmacies “Rolled Over” Prescriptions For Drugs Dispensed To At Least 1,476 ALFs And Other Residential Facilities.²⁵

162. Defendants admit that some Omnicare pharmacies dispense certain medications to certain facilities on a cycle fill basis. The last sentence of Paragraph 162 contains a characterization of the Government’s Complaint, to which no response is required. Defendants deny the remaining allegations of Paragraph 162.

163. Defendants deny the allegations of Paragraph 163.

164. Defendants deny the allegations of Paragraph 164.

165. Defendants deny the allegations of Paragraph 165.

166. Defendants deny the allegations of Paragraph 166.

167. The allegations of Paragraph 167 purport to quote or characterize information from the cited documents, exhibits created by counsel for the Government purportedly based on data produced by Omnicare. The exhibits—and the underlying data—each speak for themselves. Defendants deny the allegations of Paragraph 167 to the extent they incorrectly characterize the information in the exhibit or inaccurately compile or characterize the data on which the document purports to be based.

²⁵ Defendants deny the allegations of Heading 3.

168. The first sentence of Paragraph 168 purports to identify individuals by title only and does not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them. The second sentence of Paragraph 168 purports to quote from, characterize, or describe unidentified emails, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the emails.

169. Paragraph 169 purports to quote from, characterize, or describe unidentified emails, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the emails.

170. Defendants deny the allegations of Paragraph 170.

171. Paragraph 171 purports to quote from, characterize, or describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

172. Defendants deny the allegations of Paragraph 172.

173. Paragraph 173 purports to quote from, characterize, or describe unidentified documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

B. Omnicare Dispensed Prescription Drugs To Residents Of ALFs And Other Residential Facilities Based On Records That Did Not Constitute Valid Prescriptions.²⁶

174. Defendants deny the allegations of Paragraph 174.

175. Defendants deny the allegations of Paragraph 175.

²⁶ Defendants deny the allegations of Heading B.

176. Defendants deny the allegations of Paragraph 176.

177. Paragraph 177 purports to quote from, characterize, or describe unidentified testimony, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the testimony.

178. Paragraph 178 identifies individuals by title only and does not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them.

179. Defendants deny the allegations of Paragraph 179.

180. Defendants deny the allegations of the first sentence of Paragraph 180. Defendants admit that, among other things, the Medication Administration Record reflects information regarding drugs administered to residents at long-term care facilities; however, Defendants are without sufficient information to admit or deny for what purpose or how each individual long-term care facility uses them. The third sentence contains conclusions of law to which no response is required. To the extent any further response is required, Defendants deny the allegations of Paragraph 180.

181. Defendants admit that at various times Omnicare customers may have provided Omnicare pharmacies with copies of medication lists/reports from hospitals or facilities. Defendants deny the remaining allegations of the first sentence of Paragraph 181. As to the second sentence, Omnicare lacks sufficient information to admit or deny the allegations, and, on that basis, denies them. The third and fourth sentences state conclusions of law, to which no response is required. To the extent a response is required, Defendants deny the allegations of the third and fourth sentences of Paragraph 181.

182. Defendants deny the allegations of the first sentence of Paragraph 182. The second sentence of Paragraph 182 states a conclusion of law, to which no response is required. To the extent a response is required, Defendants deny the allegations of the second sentence of Paragraph 182.

183. Defendants deny the allegations of Paragraph 183.

184. The allegations of Paragraph 184 of the Complaint state conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 184.

II. Defendants Knew That Omnicare Pharmacies Routinely “Rolled Over” Prescriptions And Dispensed Drugs To Residents Of ALFs And Other Residential Facilities Without Current, Valid Prescriptions, But Did Not Address The Problem Until After They Became Aware Of The Government’s Investigation.²⁷

185. Defendants deny the allegations of Paragraph 185.

186. Defendants admit that CVS acquired Omnicare on August 18, 2015. Defendants deny the remaining allegations of Paragraph 186.

187. Defendants deny the allegations of Paragraph 187.

A. Omnicare And CVS Understood That Omnicare Needed Current Prescriptions With Authorized Refills To Continue To Dispense Drugs To Residents Of ALFs And Other Residential Facilities.²⁸

188. Defendants admit that there can be differences in staffing and personnel licensure in different types of facilities and that dispensing can vary based on state law. Defendants deny the remaining allegations of Paragraph 188.

²⁷ Defendants deny the allegations of Heading II.

²⁸ Defendants deny the allegations of Heading A.

189. Paragraph 189 purports to quote from, characterize, or describe unidentified documents or testimony, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents or testimony.

190. Paragraph 190 purports to quote from, characterize, or describe an unidentified discussion; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the discussion(s).

191. Paragraph 191 purports to quote from, characterize, or describe unidentified documents or testimony, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents or testimony.

192. Paragraph 192 purports to quote from, characterize, or describe unidentified documents or testimony, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents or testimony.

193. Paragraph 193 purports to quote from, characterize, or describe unidentified documents or testimony, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents or testimony.

194. Paragraph 194 purports to quote from, characterize, or describe unidentified documents or testimony, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents or testimony.

195. Paragraph 195 purports to quote from, characterize, or describe unidentified documents or testimony, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents or testimony.

B. Omnicare And CVS Knew That Omnicare Pharmacies Routinely “Rolled Over” Prescriptions And Dispensed Drugs To Residents Of ALFs And Other Residential Facilities Without Current, Valid Prescriptions.²⁹

196. Defendants deny the allegations of Paragraph 196.

1. State Boards Of Pharmacy Alerted Omnicare And CVS That Omnicare Pharmacies Dispensed Drugs Without Valid Prescriptions.³⁰

197. Paragraph 197 purports to quote from, characterize, or describe unidentified findings, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the findings. Defendants admit that Omnicare has had communications with state regulatory agencies but deny any attempt by Plaintiff to characterize those communications. Defendants deny any remaining allegations of Paragraph 197.

198. Paragraph 198 purports to quote from, characterize, or describe unidentified findings and a related, unidentified stipulation. These documents speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the underlying findings and stipulation.

²⁹ Defendants deny the allegations of Heading B.

³⁰ Defendants deny the allegations of Heading 1.

199. Paragraph 199 purports to quote from, characterize, or describe a letter, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the letter.

200. Paragraph 200 purports to quote from, characterize, or describe unidentified audit-related documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

201. The first, third and fourth sentences of Paragraph 216 purport to quote from, characterize, or describe unidentified documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents. Defendants deny the allegations of the second, fifth, sixth, and seventh sentences of Paragraph 201.

2. Third-Party Audits Of Omnicare Pharmacies Found That Omnicare Dispensed Drugs Without Valid Prescriptions.³¹

202. Paragraph 202 offers generalized assertions regarding unspecified findings by unspecified insurance plans; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them. Defendants further deny the allegations to the extent they are incomplete or inconsistent with the underlying findings.

203. Paragraph 203 purports to quote from, characterize, or describe unidentified audit-related documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

³¹ Defendants deny the allegations of Heading 2.

204. Paragraph 204 purports to quote from, characterize, or describe unidentified audit-related documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

205. Paragraph 205 purports to quote from, characterize, or describe unidentified audit-related documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

206. Paragraph 206 purports to quote from, characterize, or describe unidentified audit-related documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

207. Paragraph 207 purports to quote from, characterize, or describe unidentified audit-related documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

3. Omnicare's Internal Audits Showed That Its Pharmacies Dispensed Drugs Without Valid Prescriptions.³²

208. Paragraph 208 offers generalized assertions regarding “regular” or “comprehensive” audits. Absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them.

209. Paragraph 209 purports to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

³² Defendants deny the allegations of Heading 3.

210. Paragraph 210 purports to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

211. Paragraph 211 purports to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

4. Omnicare Pharmacy Staff Alerted Management That Omnicare's Computer Systems "Rolled Over" Prescriptions For Drugs Dispensed To Residents Of ALFs And Other Residential Facilities.³³

212. Defendants deny the allegations of Paragraph 212.

213. Paragraph 213 identifies individuals by title only and does not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them.

214. Paragraph 214 purports to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

5. Residential Facilities Alerted Omnicare That Its Pharmacies Dispensed Drugs Without Valid Prescriptions.³⁴

³³ Heading 4 purports to identify individuals by title only and does not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them. Defendants further deny the allegations to the extent that they are incomplete or inconsistent with the unidentified, underlying discussions referenced in the Heading.

³⁴ Defendants deny the allegations of Heading 5.

215. Paragraph 215 offers generalized assertions regarding unspecified communications from unspecified facilities. Absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them. Defendants further deny the allegations to the extent they are incomplete or inconsistent with the underlying communications.

216. Paragraph 216 purports to quote from, characterize, or describe unidentified documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

217. Paragraph 217 purports to quote from, characterize, or describe unidentified documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the documents.

218. Paragraph 218 purports to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

C. CVS And Omnicare Operations And Compliance Managers Discussed Omnicare's Practice Of "Rolling Over" Prescriptions For Drugs Dispensed To Residents Of ALFs And Other Residential Facilities.³⁵

219. The allegations of Paragraph 219 purport to characterize the Government's belief in what is "unsurprising," a matter about which the Defendants lack sufficient information to admit or deny, and, on that basis, deny the allegations. To the extent the allegations of Paragraph 219 purport to incorporate or summarize the preceding allegations, Defendants incorporate by

³⁵ Heading C offers generalized assertions regarding unspecified communications from unspecified individuals. Absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them. Defendants further deny the allegations to the extent they are incomplete or inconsistent with the unidentified, underlying communications.

reference their responses to Paragraphs 196–218. Defendants deny the remainder of the allegations in Paragraph 219.

220. The allegations of the first, second, third, and fourth sentences of Paragraph 220 purport to quote or characterize information from the cited document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document. With regard to the fifth sentence, Defendants admit that, in 2016, Omnicare implemented a computer-system enhancement that prevented prescriptions where the maximum quantity/refills had been exhausted from being staged for a cycle fill until new authorization was obtained. Defendants deny any remaining allegations in the fifth sentence of Paragraph 220 and, to the extent they incorporate allegations “discussed below,” Defendants incorporate by reference their responses to Paragraphs 226–233.

221. With regard to the first sentence of Paragraph 221, Defendants admit that Omnicare’s Sacramento pharmacy supplied pharmaceuticals to residents of a number of long-term care facilities during the Relevant Period. To the extent that the first sentence of Paragraph 221 purports to allege that those facilities qualify as “assisted living facilities” under California or federal law, it states a conclusion of law to which no response is required. Otherwise, the allegations of the first, second, third, fourth, and fifth sentences of Paragraph 221 purport to quote from, characterize, or describe the cited document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

222. Paragraph 222 purports to quote from, characterize, or describe the cited document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

223. The allegations of Paragraph 223 purport to quote from, characterize, or describe the cited document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

224. The allegations of Paragraph 224 purport to quote from, characterize, or describe the cited document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

225. Paragraph 225 purports to identify individuals by title only and does not provide sufficient information for the individuals to be identified; absent further specificity, Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them.

D. Despite Defendants' Awareness Of Omnicare's Illegal Dispensing Practices, Defendants Did Not Address The System-Wide "Rollover" Problem Until After The Government's Investigation Began.³⁶

226. Defendants deny the allegations of Paragraph 226.

227. Regarding the first sentence of Paragraph 227, Defendants admit that by 2016, Omnicare recoded the Retirement field for every Assisted Living Facility customer in OmniDX to "Y" to require entry of maximum quantity or refills. Otherwise, Defendants deny the allegations in the first sentence of Paragraph 227. The second sentence of Paragraph 227 purports to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the underlying document.

228. Regarding the first sentence of Paragraph 228, Defendants admit that Omnicare implemented a computer-system enhancement that made the "Retirement" setting default to "Y"

³⁶ Defendants deny the allegations of Heading D.

during the facility setup process. Defendants deny any remaining allegations in to the first sentence of Paragraph 228. Regarding the second sentence of Paragraph 228, Defendants admit that, Omnicare implemented a process for corporate review of new facility coding. Defendants deny any remaining allegations in the second sentence of Paragraph 228.

229. Regarding the first sentence of Paragraph 229, Defendants admit that, in 2016, OmniDX programming logic was changed to not allow a cycle fill order to print for fulfillment if there were no remaining refills until a new authorization was obtained. Defendants deny any remaining allegations in the first sentence of Paragraph 229. Regarding the second sentence of Paragraph 229, Defendants admit that, in 2016, Omnicare revised its internal policy regarding the cycle-fill process. Defendants deny any remaining allegations in the second sentence of Paragraph 229. The third and fourth sentences of Paragraph 229 purport to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the underlying document.

230. Defendants deny the allegations in the first sentence of Paragraph 230. The second sentence of Paragraph 230 purports to quote from, characterize, or describe an unidentified document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the underlying document.

231. Defendants deny the allegations in the first sentence of Paragraph 231. Regarding the second sentence of Paragraph 231, Defendants admit that in early 2018 Omnicare performed a survey of pharmacies that used the Oasis system to determine whether, according to the particular pharmacist-in-charge's understanding of state facility licensure and state pharmacy

practice, the default customer class associated with each facility should require a maximum prescribed quantity or refills. Defendants deny any remaining allegations in the second sentence of Paragraph 231. The third sentence of Paragraph 231 purports to quote from, characterize, or describe the cited document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the underlying document.

232. Defendants deny the allegations of Paragraph 232.

233. Defendants deny the allegations of Paragraph 233.

III. Omnicare Put At Risk The Health Of Elderly And Disabled Residents Of ALFs And Other Residential Facilities By Routinely Dispensing Prescription Drugs To Them Without Valid Prescriptions.³⁷

234. Defendants deny the allegations of Paragraph 234.

235. Paragraph 235 purports to describe obligations of physicians. Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them.

236. Defendants deny the allegations of the first sentence of Paragraph 236. The second sentence of Paragraph 236, purports to summarize and characterize statutory or regulatory provisions and to state conclusions of law, to which no response is required. To the extent a response is required, Defendants deny the allegations of the second sentence of Paragraph 236 to the extent they are inconsistent with the underlying statutes and regulations. The third sentence of Paragraph 236 purports to describe the impact of unidentified drugs on unidentified patients. Defendants lack knowledge or information sufficient to admit or deny the allegations and, on that basis, deny them.

³⁷ Defendants deny the allegations of Heading III.

237. Defendants admit that Omnicare dispenses prescription drugs that are indicated for treatment of patients with dementia, hypertension, and diabetes and that certain drugs may have label requirements for monitoring. Defendants deny any remaining allegations of Paragraph 237.

IV. Omnicare’s Illegal Practice Of “Rolling Over” Prescriptions And Dispensing Drugs Without Current, Valid Authorization Resulted In The Submission Of Hundreds Of Thousands Of False Claims To Federal Healthcare Programs.³⁸

238. Paragraph 238 states a conclusion of law, to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 238.

239. The first sentence of Paragraph 239 states a conclusion of law to which no response is required. To the extent a response is required, Defendants deny the allegations of the first sentence of Paragraph 239. The second, third, and fourth sentences of Paragraph 239 purport to summarize statutory or regulatory provisions and to state conclusions of law, to which no response is required. To the extent a response is required, Defendants deny the allegations of the second, third, and fourth sentences of Paragraph 239 to the extent they are inconsistent with the underlying statutes and regulations.

240. Defendants incorporate by reference their responses to Paragraphs 26–65. To the extent a further response is required, Defendants deny the allegations in Paragraph 240.

241. Paragraph 241 purports to describe obligations of Part D Sponsors and CMS and to state conclusions of law, to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to admit or deny the allegations in the first sentence of Paragraph 241 and, on that basis, deny them. Defendants further deny the allegations in Paragraph 241 to the extent they are inconsistent with any underlying statutes and

³⁸ Defendants deny the allegations of Heading IV.

regulations. Defendants lack knowledge or information sufficient to admit or deny the allegations in the second sentence of Paragraph 241 and, on that basis, deny them.

242. Paragraph 242 states conclusions of law to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 242.

243. Defendants deny the allegations of Paragraph 243.

244. Regarding the first sentence of Paragraph 244, Defendants admit that some of the information Omnicare submitted in claims for payment was originally stored in the OmniDX or Oasis computer dispensing systems. Defendants deny any remaining allegations of the first sentence of Paragraph 244. Defendants deny the allegations of the second and third sentences of Paragraph 244.

245. Defendants deny the allegations of Paragraph 245.

246. Defendants lack knowledge or information sufficient to admit or deny the allegations of Paragraph 246 and, on that basis, deny them.

247. Regarding the first sentence of Paragraph 247, Defendants incorporate by reference their response to Paragraphs 34–43, 49–51, 58–59, 65. To the extent a further response is required, Defendants deny the allegations in the first sentence of paragraph 247. Defendants deny the allegations in the second sentence of Paragraph 247.

248. Defendants deny the allegations of Paragraph 248.

V. Defendants’ Fraudulent Conduct Was Material To Federal Healthcare Programs’ Payment Decisions.³⁹

249. The first sentence of Paragraph 249 states conclusions of law to which no response is required. To the extent any response is required, Defendants deny the allegations in

³⁹ Heading V states conclusions of law to which no response is required. To the extent any response is required, Defendants deny the allegations of Heading V.

the first sentence of Paragraph 249. Defendants deny the allegations in the second sentence of Paragraph 249.

250. Defendants admit that Federal Healthcare Programs and Part D Plans conduct audits of pharmacies, including Omnicare pharmacies. Defendants are without sufficient information to admit or deny the allegations of Paragraph 250 regarding the motivations behind such audits and, on that basis, deny the allegations of Paragraph 250.

251. Defendants are without sufficient information to admit or deny the allegations of Paragraph 251 and, on that basis, deny the allegations.

252. Paragraph 252 purports to quote from, characterize, or describe unidentified documents, which speak for themselves; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the underlying documents.

253. The allegations of Paragraph 253 consist of a hypothetical to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 253.

254. Paragraph 254 purports to quote from, characterize, or describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

255. Paragraph 255 purports to quote from, characterize, or describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

256. Paragraph 256 states conclusions of law to which no response is required. To the extent any response is required, Defendants deny the allegations of Paragraph 256.

257. Regarding the first sentence of Paragraph 257, Defendants incorporate by reference their responses to Paragraphs 34–43, 49–51, 58–59, 65. To the extent a further response is required, Defendants deny the allegations in the first sentence of Paragraph 257. The second sentence of Paragraph 257 states a conclusion of law to which no response is required. To the extent any response is required, Defendants deny the allegations in the second sentence of Paragraph 257.

VI. False Claims Submitted By Omnicare⁴⁰

258. Defendants deny the allegations of Paragraph 258.

259. The allegations of Paragraph 259 purport to quote or characterize information from the cited document, an exhibit created by counsel for the Government purportedly based on data produced by Omnicare. The exhibit—and the underlying data—each speak for themselves. Defendants deny the allegations of Paragraph 259 to the extent they incorrectly characterize the information in the exhibit or inaccurately compile or characterize the data on which the document purports to be based. Defendants deny that any of the prescription dispenses chronicled in the cited document were “invalid.”

260. Defendants deny the allegations of Paragraph 260.

261. Defendants deny the allegations of Paragraph 261.

262. The allegations of Paragraph 262 relate in part to the Government’s Exhibit, which purports to summarize information pulled from Omnicare’s dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 262 to the extent they characterize information beyond what is

⁴⁰ Defendants deny the allegations of Heading VI.

contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete.

263. The allegations of Paragraph 263 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 263 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete. The fourth, fifth, and sixth sentences of Paragraph 263 purport to quote from, characterize, or describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

264. The allegations of Paragraph 264 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 264 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete.

265. The allegations of Paragraph 265 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the

allegations of Paragraph 265 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete.

266. The allegations of Paragraph 266 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 266 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete. The fourth and fifth sentences of Paragraph 266 purport to quote from, characterize, or describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

267. The allegations of Paragraph 267 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 267 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete.

268. The allegations of Paragraph 268 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular

prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 268 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete.

269. The allegations of Paragraph 269 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 269 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete.

270. The allegations of Paragraph 270 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 270 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete. The third sentence of Paragraph 270 purports to quote from, characterize, or describe a document, which speaks for itself; to the extent a response is required, Defendants deny the allegations to the extent they are incomplete or inconsistent with the document.

271. The allegations of Paragraph 271 relate in part to the Government's Exhibit, which purports to summarize information pulled from Omnicare's dispensing systems regarding the facility name, drug name, patient name, and Omnicare location involved in particular

prescription dispenses. Defendants do not deny the veracity of that information, but deny the allegations of Paragraph 271 to the extent they characterize information beyond what is contained in the data on which the Exhibit was based, are inconsistent with that data, or are otherwise incomplete.

COUNT I

272. Defendants incorporate by reference their responses to Paragraphs 1–271.

273. Defendants admit that the United States purports to bring a claim against them pursuant to 31 U.S.C. § 3729(a)(1)(A). Defendants deny that such a claim is valid.

274. Defendants deny the allegations of Paragraph 274.

275. Defendants deny the allegations of Paragraph 275.

276. Defendants deny the allegations of Paragraph 276.

277. Defendants deny the allegations of Paragraph 277.

COUNT II

278. Defendants incorporate by reference their responses to Paragraphs 1–277.

279. Defendants admit that the United States purports to bring a claim against them pursuant to 31 U.S.C. § 3729(a)(1)(B). Defendants deny that such a claim is valid.

280. Defendants deny the allegations of Paragraph 280.

281. Defendants deny the allegations of Paragraph 281.

282. Defendants deny the allegations of Paragraph 282.

COUNT III

283. Defendants incorporate by reference their responses to Paragraphs 1–282.

284. Defendants admit that the United States purports to bring a claim against them pursuant to 31 U.S.C. § 3729(a)(1)(G). Defendants deny that such a claim is valid.

285. Defendants deny the allegations of Paragraph 285.

286. Defendants deny the allegations of Paragraph 286.

COUNT IV

287. Defendants incorporate by reference their responses to Paragraphs 1–286.

288. Defendants admit that the United States purports to bring a claim against them for “payment by mistake of fact.” Defendants deny that such a claim is valid.

289. Defendants deny the allegations of Paragraph 289.

290. Defendants deny the allegations of Paragraph 290.

COUNT V

291. Defendants incorporate by reference their responses to Paragraphs 1–290.

292. Regarding the first sentence of Paragraph 292, Defendants admit that the United States purports to bring a claim against them for unjust enrichment. Defendants deny that such a claim is valid. Defendants deny the allegations of the second sentence of Paragraph 292.

AFFIRMATIVE DEFENSES

Defendants assert the following affirmative defenses. Defendants undertake the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Defendants reserve the right to amend this Answer if additional defenses, counterclaims, or third party claims become apparent through the course of this action. Further, Defendants reserve the right to assert any and all defenses on which it does not bear the burden of proof, including but not limited to the defense that the Government has failed to allege facts or a cause of action sufficient to support a claim for attorney’s fees and costs, or treble damages.

FIRST DEFENSE

The Government's claims are barred, in whole or in part, by government knowledge and/or the doctrines of waiver, and/or estoppel.

SECOND DEFENSE

The Government's claims fail because any and all actions taken by Defendants with respect to any of the matters alleged in the Government's Complaint were taken in accordance with established industry practice.

THIRD DEFENSE

The Government's claims fail because, at all times relevant to the Government's Complaint, Defendants complied with all applicable federal and state regulations.

FOURTH DEFENSE

The Government's claims are barred, in whole or in part, because they rely upon ambiguous provisions of law and such ambiguities must be resolved in Defendants' favor.

FIFTH DEFENSE

The Government's claims are barred, in whole or in part, by the doctrine of consent and/or ratification as the Government has ratified the alleged conduct of Defendants complained of in the Government's Complaint by failing to take any action despite its knowledge of the conduct.

SIXTH DEFENSE

The Government's asserted damages, if any, may have been caused by, or were the result of, actions or inactions of parties other than Defendants or parties over whom Defendants had no authority or control.

SEVENTH DEFENSE

The Government's claims for damages are barred, in whole or in part, to the extent that the statutes it seeks to enforce, or the damages and penalties she seeks to recover, violate Defendants' constitutional rights, including under the Excessive Fines Clause, or any other constitutional provision.

EIGHTH DEFENSE

The Government's claims for damages fail because it has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Defendants as alleged in the Government's Complaint.

NINTH DEFENSE

The Government's claims are barred, in whole or in part, by the applicable statute of limitations.

TENTH DEFENSE

The misrepresentations alleged in the Government's Complaint are not material, including as shown by the Government's conduct.

ELEVENTH DEFENSE

Defendants are not vicariously liable for the acts alleged in the Government's Complaint.

TWELFTH DEFENSE

The Government's claims are barred, in whole or in part, as a result of set-off of monies previously paid by Defendants.

Dated: April 16, 2021

Respectfully submitted,

WILLIAMS & CONNOLLY LLP

/s/ Enu Mainigi

Enu Mainigi (*pro hac vice*)

Holly Conley (*pro hac vice*)

Benjamin Hazelwood (Bar No. 5001508)

725 Twelfth Street, N.W.

Washington, DC 20005

(202) 434-5000

For Matters in New York:

WILLIAMS & CONNOLLY LLP

650 Fifth Avenue

Suite 1500

New York, NY 10019

*Attorneys for Defendants Omnicare, Inc. and CVS
Health Corp.*